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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,257	04/09/2001	Michael Buchanan	P66570US0	3204

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EXAMINER
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ART UNIT	PAPER NUMBER
1614	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/833,257	Applicant(s) BUCHANAN ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 12-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions Acknowledged

1. Acknowledgement is made of applicants election of Group II invention without traverse. Therefore, Claims 14-26 will also be examined along with the elected invention.

It is noted to applicants that claim 11 which is a dependent claim of claim 1 was inadvertently included in Group II invention. Therefore, it is proper not to examine claim 11 as being drawn to a non-elected invention. In addition, claims 1-9 and 27-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 10, 12-13 and 14-26 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "A method of correcting the inhibition of endogenours 13-HODE synthesis by omega-3 fatty acids by incorporating 13-HODE into formulations of omega-3 fatty acids". It appears essential in view of the instant specification (page 19, lines 19-23) 13-HODE is administered exogenously to "compensate for any suppression of endogenous 13-HODE synthesis which can occur as a result of administration of omega-3 fatty acids". There is no indication in present claim 10, however that said 13-HODE is administered exogenously to a

patient in need of such treatment to correct the inhibition of endogeneous 13-HODE synthesis. It appears that Claim 10 is being incomplete for omitting essential steps and is consequently unclear. Furthermore, it is not clear how the incorporation of 13-HODE into formulations of omega-3 fatty acids is enable of "correcting the inhibition of endogenous 13-HODE synthesis by omega-3 fatty acids". Applicant is requested to clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 14-15, 18-20 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Carlsson et al. (WO 99/44585).

Carlsson discloses a topical formulation comprising 13-HODE, CPL-Evening Primrose oil, ascorbyl palmitate, thickener, emulsifier and preservative.

Regarding claims 19 and 20 limitation, since claims 19 and 20 are not limited to isolated or purified forms of fatty acids, the referenced composition containing Evening Primrose oil which contains gamma linolenic acid (GLA) and linolenic acid (LA) anticipates the claimed composition.

Although the composition of Carlsson differs from the claimed composition in "for oral administration", applicant's statement of such intended use or purpose is not limiting to the

interpretation of the composition claim. Therefore, the reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 10, 12-13 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (J Invest Dermatol, 1990, 94:353-358).

The claims appear to be directed to a method of correcting the inhibition of endogenous 13-HODE synthesis by omega-3 fatty acids by coadministering 13-HODE and omega-3 fatty acid to a patient in need of such correction (claims 10 and 12-13); and a composition comprising 13-HODE and omega-3 fatty acids, for example EPA, DHA, ethyl-EPA and ethyl-DHA (claims 24-26).

Miller teaches or suggests the use of 13-HODE to reverse the n-3 PUFA (e.g., eicosapentaenoic acid and docosahexaenoic acid) induced guinea pig skin hyperproliferation. The reference teaches or suggests that the induction of epidermal hyperproliferation by topical n-3 pufa links to decreased levels of 13-HODE (abstract and page 356, column 2, para. 1), and that exogenous application of 13-HODE would be beneficial in reversing the suppression of 13-HODEsynthesis (see Discussion, page 356-357 and page 19, lines 19-23 of the instant specification).

One having ordinary skill in the art would have known that the administration of 13-HODE could reverse the suppression of endogenous 13-HODE synthesis induced by n-3 PUFA such as EPA and DHA. One having ordinary skill in the art would have expected that the co-administration of 13-HODE with omega-3 fatty acid (e.g., EPA and DHA) could correct the inhibition of endogenous 13-HODE synthesis by omega-3 fatty acid. Furthermore, one having ordinary skill in the art would have been motivated to modify the teaching of Miller such that the side effect induced by omega-3 fatty acid would be greatly reduced.

In respective claim 12 and 26, one having ordinary skill in the art would have been motivated to select the claimed compound such as ethyl-EPA and ethyl-DHA with the expectation that ethyl ester of EPA and ethyl ester of DHA would not significantly alter the analogous properties of compound of the reference due to a close structural similarity of the compounds.

5. Claims 16-17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streber (US 5102912) in view of Carlsson et al. (WO 99/44585).

The claims (claims 16-17 and 21-22) read on a pharmaceutical composition comprising 13-HODE and carriers, wherein the daily dose of 13-HODE is equal to or less than 100mg (claim 16); wherein carriers is a mono, di- or triglyceride oil (claim 17); wherein the composition is administered in the form of tablets, dragees, capsules, solutions, suspensions and lyophilized composition (claim 21); and wherein the composition further comprises a fat-soluble antioxidant, for example ascorbyl palmitate, tocopherols and ascorbic acid in the presence of lecithin (claim 22).

Streber implicitly teaches a pharmaceutical composition in tablet form contains 13-HODE (13-hydroxy-9(cis)-11(trans)-octadecadienoic acid (column 3, line 14 and line 46). The reference also implicitly teaches that (i) the composition is administered orally by tablets, capsules or dragees or by injections; (ii) 13-HODE can be formulated in oily materials, for example soya oil and triglyceride (column 3, lines 37-41 and lines 61-65 and column 4, lines 1-9); and (iii) the composition can be administered in a single dose in an amount of about 50.0 to 200mg, or in daily dose for an adult person in about 100 to 1000mg (column 3, lines 52-56).

The teaching of Carlsson has been discussed in above 102(a) rejection. In addition, Carlson teaches or suggests that the use of phospholipids as a suitable oily materials in 13-HODE formulation (page 5, line 9).

The teaching of Streber differs from the claimed invention in the incorporation of phospholipids (lecithin) in 13-HODE formulation. To incorporate such teaching into the teaching of Streber, would have been obvious in view of Carlsson who teaches or suggests the use of phospholipids (lecithin) in 13-HODE formulation.

Above references in combination make clear that the incorporation of various oily materials such as vegetable oils (e.g., evening primrose oil, soybean, etc...), mono-, di- or triglyceride and phospholipids (lecithin) in 13-HODE formulation is old and well known. Above references in combination also make clear that the formulation of 13-HODE into topical form, tablet, capsule, dragees or solutions is old and well known. One having having ordinary skill in the art would have expected in view of Carlsson that various oily materials including vegetable oils (e.g., evening primrose oil, soybean oil, etc...), mono-, di- and triacylglycerols, phospholipids can be used to formulate different 13-HODE formulations including tablets, capsules, solution, dragees and solutions. One having ordinary skill in the art would have been motivated to incorporate phospholipids (lecitihin) in 13-HODE composition, with the reasonable expectation of success, such that the pharmacological profile would be enhanced.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al. (WO 99/44585).

The claims reads on a pharmaceutical composition comprising 13-HODE and omega-3 fatty acids.

The teaching of Carlsson has been discussed in preceding comments. In addition, Carlsson teaches or suggests the use of canola oil as a suitable oily material in 13-HODE formulation (page 5, line 2).

The teaching of Carlsson differs from the claimed invention in the use of omega-3 fatty acid. However, similarly to the examiner's preceding comments, the selection of suitable oil, for example canola oil, among various oily materials described in Carlssson to prepare various 13-HODE formulation is well considered within the skill of the artisan. One having ordinary skill in the art would have known that canola oil is a natural source for omega-3 fatty acid. Since the present claims do not specifically state that omega-3 fatty acid must essentially be used in the isolated form. Thus, the reference makes obvious the claimed invention.

Even if the claimed composition includes the isolated or purified omega-3 fatty acid, such incorporation of omega-3 fatty acid would have been apparent to a person skilled in the art as taught or suggested by Carlsson who relates to the use of canola oil, which contains omega-3 fatty acid called alpha-linolenic acid, in 13-HODE formulation.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600